

REMARKS/ARGUMENTS

Claim 1-9 are currently pending in this application. Claim 6 has been amended to more clearly recite the elements of the claimed invention. No new matter has been added by this Amendment.

Amendments to the Specification

In the specification, the paragraphs starting on page 6, line 9 and the page 7, line 3 have been amended to correct minor typographical and grammatical errors. The paragraph starting on page 5, line 26 has been amended to further specify that fluid may be introduced into the catheter lumen through a proximal-end catheter port 150. Support for this amendment to the specification may be found, for example, on page 3, lines 20-22. Therefore, it is respectfully submitted that no new matter has been added by these amendments to the specification.

Objection to the Drawings

The Examiner objected to the drawings under 37 C.F.R. § 1.83(a) for failure to show every feature of the claimed invention. In particular, the Examiner required that the drawings show the proximal-end catheter port. This objection has respectfully been overcome.

Fig. 5 has been amended to include reference number “150” that designates the proximal-end catheter port 150. As discussed above, support for this amendment may be found, for example, on page 3, lines 20-22. Therefore, Applicants respectfully request that the objection to the drawings be withdrawn. Also, reference number 1000 and its lead line have been repositioned so it more accurately designates the proximal end user control handle (see specification at page 8, lines 18-23).

Rejections Under 35 U.S.C. § 102(b)

The Examiner has rejected claims 6, 8, and 9 under 35 U.S.C. § 102(b), (“Section 102(b)”), as being anticipated by United States Patent No. 5,700,243 to Narciso, Jr. (“Narciso”). Applicants respectfully traverse this rejection.

Narciso discloses a balloon-type catheter with an integral fiber-optic assembly and a perfusion channel to allow fluid to flow around the inflated balloon during photo-irradiation. (Narciso, column 2, lines 14-18). A fiber optic bundle 17 is attached by an optical connector 18 to the catheter 12. (Narciso, column 3, lines 28-30.)

In contrast, claim 6 recites that the fiber optic bundle is adapted “for introduction into the catheter lumen after the catheter’s distal-end sleeve is placed within the target region.”

Therefore, claim 6 recites that the fiber optic bundle is separate from and insertable into the catheter lumen. There is no disclosure in Narciso that the fiber optic bundle of Narciso be separate from and insertable into the catheter lumen. Therefore, because Narciso does not disclose each and every element of the claimed invention, Narciso does not anticipate claim 6 of the present application or claims 8 and 9, both of which depend on claim 6.

The Examiner has also rejected claims 6, 8, and 9 under Section 102(b) as being anticipated by United States Patent No. 5,445,608 to Chen et al. ("Chen"). Applicants respectfully traverse this rejection.

Figs. 12A-D of Chen show an implantable probe 174 with a catheter 176 having a central lumen 182 through which a guidewire may be inserted. At the end of the catheter is a light distribution tip 178, which closes off the distal end of the catheter. Therefore, no portion of a guidewire used with the probe of Chen is able to be advanced past or through the light distribution tip since Chen does not disclose an opening through which the guidewire can be advanced through the light distribution tip of the catheter. Optical fibers 180 are arranged around the central lumen within their own individual lumens, and are adhesively bonded or heat-fused to the light distribution tip at the distal end of the catheter. (Chen, column 19, lines 48-59.)

In contrast, claim 6 recites that the catheter has a lumen "through which lumen catheter can be advanced over the guidewire to position the catheter's distal-end sleeve within the target region ..." Therefore, claim 6 recites that the guidewire be positioned in the target region before the catheter is positioned in the target region, allowing the catheter to be advanced over the guidewire. Chen does not disclose this element of the invention. In fact, Chen teaches away from this aspect of the invention. More specifically, by teaching that the light distribution tip 178 closes off the distal end of the catheter, Chen does not disclose an opening through which the catheter can be advanced over the guidewire.

Furthermore, in Chen the ends of the optic fibers are adhesively bonded or heat-fused to the light distribution tip at the distal end of the catheter. As discussed above, claim 6 recites that the fiber optic bundle be separate from and insertable into the catheter lumen after the catheter's translucent distal-end sleeve is positioned or placed within the target region. Therefore, by disclosing that the optic fibers are fused to the light distribution tip, *i.e.*, not separate from the catheter, Chen does not disclose this element of claim 6. Instead, Chen teaches away from the present invention wherein the optic fibers are separate from the

catheter having a translucent distal-end sleeve so that the optic fibers can be inserted into the catheter lumen after the catheter's translucent distal-end sleeve is positioned within the target region.

Since Narciso and Chen both fail to disclose each and every element of claim 6, Applicants respectfully submit that Narciso and Chen fail to anticipate claim 6, and Applicants request that these rejections to claim 6 be withdrawn. Furthermore, since claims 8 and 9 depend from claim 6, these claims are also not anticipated by Narciso or Chen. Therefore, Applicants also respectfully request that the rejections to claims 8 and 9 be withdrawn.

Rejections Under 35 U.S.C. § 103(a)

The Examiner has rejected claims 1-5 under 35 U.S.C. § 103(a) ("Section 103(a)") as being unpatentable over United States Patent No. Re. 34,544 to Spears ("Spears") in combination with Chen. Applicants respectfully traverse this rejection.

Spears discloses a method of treating atherosclerosis by utilizing a balloon-type catheter to treat plaques. The device in Spears comprises a catheter 12 with a hollow glass fiber 24 attached to the distal end of the catheter 12. An optical fiber 20 is disposed within the hollow glass fiber 24. As the Examiner has acknowledged, Spears does not disclose insertion of the optic fiber into the catheter lumen. Moreover, Spears does not disclose or suggest that the optical fiber is separate from and insertable into the catheter having a translucent distal-end sleeve after the catheter's distal-end sleeve is positioned within the target region. Thus, Spears does not disclose or suggest the present invention. Furthermore, as discussed above, Chen fails to disclose or suggest that an optical fiber that is separate from and insertable into a catheter having a translucent distal-end sleeve after the catheter's distal-end sleeve is positioned within the target region. Therefore, both Spears and Chen fail to disclose or suggest, either alone or in combination, the steps of "introducing through the catheter a fiber-optic bundle" after a catheter having a translucent distal-end sleeve has advanced over a guidewire to access the target region, as recited in claim 1.

In addition, Applicants respectfully submit that Spears in fact teaches away from having an optical fiber that is separate from the catheter. Figure 1 of Spears shows that optical fiber 20 is disposed alongside the longitudinal axis of the catheter within the catheter lumen and that a movable guidewire is also disposed in the catheter lumen at the same time. By showing that the guidewire and the optical fiber are disposed within the catheter lumen

concurrently, Spears teaches away from removing a guidewire and then inserting an optical fiber. Therefore, there is no motivation to combine Spears with a teaching to insert an optical bundle into a catheter after the catheter is positioned within a target region and after the guidewire is removed.

Therefore, for the reasons stated above, Applicants respectfully submit that the rejection to claim 1 has been traversed, and Applicants respectfully request that this rejection to claim 1, as well as dependent claims 2-5 be withdrawn.

The Examiner has rejected claims 6 and 7 have been rejected under Section 103(a) as being unpatentable over Chen. As noted above, Chen fails to disclose, teach, or suggest the step of introducing a fiber optic bundle into a catheter having a translucent distal-end sleeve after the catheter has been positioned within the target region. Therefore, Chen fails to disclose or suggest all of the elements of claim 6. As claim 7 depends from independent claim 6, claim 7 is also patentable over Chen.

The Examiner has also rejected claims 6 and 7 under Section 103(a) as being unpatentable over Narcisco. As discussed above, Narcisco also fails to disclose, teach, or suggest the step of introducing a fiber optic bundle into a catheter after the distal-end sleeve has been positioned within the target region. Thus, Narcisco does not render claims 6 and 7 as obvious.

Therefore, for at least the reasons above, Applicants respectfully request that these rejections to claims 6 and 7 be withdrawn.

Favorable consideration of Applicants' claimed invention is respectfully solicited. It is respectfully believed that the present claims are in condition for allowance, early notice of which would be appreciated. No fees are believed due with the submission of this response. Should any fees be due, however, please charge such fees to Pennie & Edmonds LLP Account No. 16-1150.

Respectfully submitted,

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APPENDIX

Replacement Sheet & Annotated Sheet Showing Changes

Amendment

Application No. 09/816,832
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NY2: 1457972.1

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